blue matter

July Oncology News Roundup

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Blue Matter Consulting is tracking oncology market trends on a daily basis, and looks back each month to highlight the newsworthy events shaping our current and future oncology market landscape.

Crucial Astra Zeneca IO study fails to show clinical benefit

The biggest oncology news of July is also the most recent, as AZ's MYSTIC study reportedly failed to demonstrate the clinical benefit of IO therapy over chemotherapy in frontline NSCLC. Relative to platinum-based standard-of-care, MYSTIC failed to show progression-free survival (PFS) benefit for AZ's PD-L1 therapy, Imfinzi, either as a monotherapy or in combination with the CTLA-4 antibody, tremelimumab. AZ is quick to emphasize that the trial remains underway and scheduled to produce overall survival (OS) data in 2018. But the July readout nonetheless hampers AZ's IO market potential and casts doubt over the general promise of PD1/L1+CTLA4 combination regimens.

Biosimilars make a collective push toward US market entry

July was a very successful month for oncology biosimilars preparing for market entry, characterized by a pair of ODAC endorsements and a successful trial readout. On the 13th, the Oncologic Drugs Advisory Committee (ODAC) unanimously voted in favor of approving Amgen's bevacizumab biosimilar and Mylan's trastuzumab biosimilar. Pfizer then followed up with positive top-line results demonstrating its own biosimilar's equivalence to bevacizumab in objective response rate in patients with non-squamous NSCLC. In all three cases, there were no clinically meaningful differences found between the biosimilar and reference product.

Keytruda faces multiple clinical setbacks

Keytruda faced a pair of setbacks in July following a multi-year run of consistent clinical success. The FDA placed a clinical hold on 3 separate multiple myeloma studies, determining that "the risks of Keytruda plus pomalidomide or lenalidomide outweigh any potential benefit for patients with multiple myeloma." Weeks later, Merck announced that Keytruda failed to meet the primary endpoint of overall survival in patients with previously treated metastatic head and neck squamous cell carcinoma (HNSCC). However, it's important to note that neither of these events drastically change expectations for Keytruda: the current HNSCC indication remains unchanged, while multiple myeloma was never considered a significant market opportunity for the brand.

Nerlynx gains FDA approval for HER2+ breast cancer

The FDA approved Nerlynx (neratinib) as the first extended adjuvant therapy for early-stage HER2+ breast cancer patients who have been previously treated with Herceptin. The approval is based on Nerlynx improvement in invasive disease-free survival (iDFS), demonstrating 94.2% iDFS at 2 years compared with 91.9% iDFS with placebo. The Nerlynx pivotal data also sets a critical benchmark margin of benefit to consider during the regulatory review of Perjeta, tested in combination with Herceptin in early-stage HER2+ patients following surgery. The Perjeta combination demonstrated a 94.1% iDFS at 3 years compared with 93.2% iDFS for the Herceptin monotherapy arm.

JULY HONORABLE MENTIONS

- The ODAC unanimously voted in support of approving Novartis' CAR-T therapy in pediatric patients with b-cell ALL
- CMS issues a proposal designed to curtail hospital profits generated from the 340B Drug Pricing Program
- Takeda secured a significant victory in US appeals court, extending Velcade's patent from 2017 until 2022
- Merck agreed to pay up to $8.4B in a development and partnership deal with AZ, centered around its PARP (Lynparza) and MEK (selumetinib) therapies